

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

GALDERMA LABORATORIES, L.P. §
and GALDERMA S.A., §
§
§
v. § ACTION NO. 4:08-CV-115-Y
§
ACTAVIS MID-ATLANTIC, L.L.C., §

ORDER GRANTING JOINT MOTION FOR
ENTRY OF STIPULATED PROTECTIVE ORDER
(with special instructions to the clerk)

Pending before the Court is the parties' Joint Motion for Entry of Stipulated Protective Order [doc. # 32], filed November 13, 2008. The Court GRANTS the motion and enters the following stipulated protective order.

WHEREAS discovery in this action may involve the disclosure of certain documents, things, and information in the possession, custody, or control of plaintiffs Galderma Laboratories, L.P., and Galderma S.A.; defendant Actavis Mid Atlantic L.L.C.; or nonparties that constitute or contain trade secrets or other confidential research, development, or proprietary business information within the meaning of Rule 26(c)(7) of the Federal Rules of Civil Procedure;

WHEREAS such confidential information must be protected in order to preserve the legitimate business interests of the

parties or nonparties;

WHEREAS this action involves highly technical subject matter that may require discovery of trade secrets and proprietary information pertaining to, among other things, drug formulations, manufacturing processes and techniques, scientific research and development, and other sensitive competitive information;

WHEREAS the parties, through counsel, have stipulated to the entry of this protective order for the purpose of advancing the progress of this action and to prevent unnecessary dissemination or disclosure of their respective confidential information; and

WHEREAS the parties, through counsel, stipulate that good cause exists for the entry of this protective order pursuant to Rule 26(c) to safeguard against improper disclosure or use of confidential information produced in this action;

It is hereby ORDERED that the following provisions shall govern the conduct of further proceedings in this action:

Definitions

1. The term "Protected Information" shall mean any document or other tangible thing or any electronically stored information that contains or

reveals what a party considers to be its trade secret, business confidential, or proprietary information, or personal data or information of individuals that may be protected as confidential under applicable law. In designating information as protected information, a party shall designate only its trade secrets, information that at all times has been maintained in confidence, information in which it has a proprietary interest or personal data or information that may be protected as confidential under applicable law. Each party shall act in good faith in designating information as protected information.

2. In this Stipulated Protective Order, "Galderma" shall refer collectively to Galderma, S.A., Galderma Laboratories, L.P., and their respective owning/controlling entities, parent(s), subsidiary(ies) and other affiliated companies. In this Stipulated Protective Order, "Actavis" shall refer collectively to Actavis Mid-Atlantic, LLC, and its owning/controlling entities, parent(s), subsidiary(ies) and affiliated companies.

3. This protective order establishes two categories of protected information. Information in the higher category is referred to as "highly confidential information." Information in the lower category is referred to as "confidential information." Only information that concerns the producing party's (i) research and development (including product formulation, trials, testing, and related materials) of any product, or (ii) business plans, strategies, marketing, and sales of any product may be categorized as highly confidential information. However, to the extent discoverable, information directly relating to the composition and/or formulation (but not research, development, trials, and testing) of Clobex[®] shampoo (as described in NDA No. 21-644) and the accused product (as described in ANDA No. 78-854) will constitute confidential information but not highly confidential information.

4. The term "qualified person" shall mean:

- (a) Galderma's outside counsel, their legal assistants, and members of their support staffs;

- (b) Actavis's outside counsel, their legal assistants, and members of their support staffs;
- (c) the Court and any Court personnel involved with this action;
- (d) any independent expert or consultant who is retained by counsel solely for the purpose of assisting in this action, provided such person has not provided consulting services to the producing party's competitors (as determined based on the information required by Paragraph 14);
- (e) two in-house attorneys for Galderma, namely, Quintin Cassady and Lydie Frère; and two in-house attorneys for Actavis, namely Lisa Graver and Ravinder Chahil;
- (f) two in-house technical advisors to Galderma's counsel, namely, Karine Nadau-Forcade and Sandrine Segura; and two in-house technical advisors to Actavis's counsel, namely Vivek Desai and an Actavis employee to be named later; provided such in-house technical advisors shall be qualified persons only with respect to confidential information, but not highly confidential information; and
- (g) any other person who is designated as a qualified person by order of the Court or by written agreement of the parties.

Use of Protected Information

5. Protected information shall be used solely for the purpose of this action.

6. Nothing in this protective order shall prevent any person, including a qualified person, from making use of any

information that is designated as protected information if such information:

- (a) was lawfully in his or her possession prior to receipt under the provisions of this protective order;
- (b) was or becomes available to the public other than through the action of a receiving party;
- (c) was or is obtained from a source not under an obligation of secrecy to the designating party; or
- (d) is exempted from the operation of this protective order by written consent of the designating party.

If any person disputes or challenges the designation of any information as Protected Information based upon any ground specified in subparagraphs (a) through (c), such person shall notify the party designating such information, in writing, explaining the documents/information at issue and describing in reasonable detail the specific basis of the challenge. If the producing party does not respond within ten (10) business days, all parties may use such information (upon the expiration of the ten (10) business day period) as if it were not designated as Protected Information. However, if the producing party objects within such ten (10) business day period, such information shall continue to be treated as protected information in accordance

with the provisions of this protective order until such designation is removed by order of the Court or by written consent of the designating party.

Disclosure of Protected Information

7. Protected information shall not be disclosed or made available to anyone other than a qualified person or the party who produced such protected information, except as otherwise provided in this protective order.

8. A document that contains or reveals protected information may be shown to any person indicated in such document to be its originator or author or the recipient of a copy.

9. A document that contains or reveals protected information may be copied by an independent commercial copying service, and an exhibit based upon such a document may be prepared by an independent printer or illustrator.

10. Protected information may be disclosed to official court reporters, stenographic reporters, videographers, and their respective assistants who are engaged in such proceedings as are necessary for the preparation and trial of this action.

11. Protected information may be disclosed to a witness testifying under oath if the witness is an officer, director, or

employee of the party who produced such protected information.

12. Protected information may be disclosed to a witness testifying under oath if (a) the witness was formerly an officer, director, or employee of the party who produced such protected information; (b) the protected information was in existence during the period of his or her service or employment; and (c) a foundation is established that the witness was involved in the project to which the protected information relates. However, before disclosing any protected information to such witness, the party making such disclosure shall inform the witness, on the record, that the use of such protected information is subject to the terms of this order. Except for qualified persons, the witness must sign the declaration in the form shown in attached Exhibit A, which declaration shall be included as an exhibit to such deposition, or the witness shall agree on the record to be bound by the terms of this order. If a witness refuses both options, the deposition may cease and the parties should file any necessary motions with an appropriate Court, or the parties may agree to continue the deposition on terms agreeable to all parties.

13. Nothing in this protective order shall prevent disclosure of protected information if the designating party

consents, in writing or on the record in a deposition or proceeding before the Court to such disclosure or if the Court, after notice to all parties, orders such disclosure.

14. Counsel desiring to disclose protected information to an independent expert or consultant according to paragraph 4(d) or any other person according to paragraph 4(g) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person. For those in either category, except independent trial or jury consultants, at least ten (10) business days in advance of the proposed disclosure of any Protected Information to that person, counsel shall serve on each other party, via facsimile, (a) that person's signed declaration, (b) that person's curriculum vitae or resume, and (c) a list of all companies for which that person has provided consulting services during the past four (4) years, with a general description of the nature of each consulting project. A party may object for cause to the proposed disclosure by serving a written objection upon each other party within ten (10) business days after receiving the copy of the signed declaration. Failure to timely object shall operate as a waiver of the objection. If a party objects to the proposed disclosure, the objecting party's protected information shall

not be disclosed to such person except by order of the Court or by written consent of the objecting party. In the event that a motion is made, the objecting party shall have the burden of proving that disclosure should not be made.

15. Counsel desiring to disclose protected information to a person according to paragraphs 4(e) or 4(f) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person, and produce a copy of the signed declaration to opposing counsel.

16. Anyone according to paragraph 4 who receives Galderma's protected information shall not be involved on Actavis's behalf in the preparation or prosecution of any patent application, new drug application or abbreviated new drug application that concerns Clobex® shampoo described in NDA No. 21-644 or any other Galderma product described in the protected information received by such person until three (3) years following the completion of this action (including any appeals). Anyone according to paragraph 4 who receives Actavis's protected information shall not be involved on Galderma's behalf in the preparation or prosecution of any patent application, new drug application or abbreviated new drug application that concerns the accused product described in ANDA No. 78-854 or any other

Actavis product described in the protected information received by such person until three (3) years following the completion of this action (including any appeals).

Identification and Marking of Protected Information

17. Any document or other tangible thing that contains or reveals confidential information or highly confidential information shall be labeled with the legend "CONFIDENTIAL" or the legend "HIGHLY CONFIDENTIAL" respectively. For a document, such marking shall appear on each page of the document that contains protected information. Any document or other tangible thing so labeled and the information that it contains or reveals shall be treated in accordance with the provisions of this protective order. Any protected information not reduced to documentary or physical form or which cannot be conveniently labeled shall be so designated by a party by serving a written notification on the receiving party.

18. When a party initially produces documents for inspection, no marking need be made by the producing party in advance of the inspection. For purposes of the inspection, all documents shall be treated as containing highly confidential information. After the receiving party selects specified documents for copying, the producing party shall appropriately

mark the copies of the selected documents before they are provided to the receiving party.

19. Information disclosed at the deposition of a party or one of its present or former officers, directors, employees, or agents may be designated as confidential information or highly confidential information by that party either (a) on the record or (b) by serving a written notification on each other party within fifteen (15) days of receipt of the transcript by counsel for the designating party. Such written notification shall identify the specific pages and lines of the transcript that contain confidential information or highly confidential information. A copy of such written notification shall be attached to the face of the transcript and each copy of the transcript in the possession, custody, or control of any qualified person. All information disclosed during a deposition shall be treated as highly confidential information until at least twenty (20) days after a transcript of the deposition is received by counsel. A deponent may review the transcript of his or her deposition at any time.

20. Only qualified persons, the deponent, and the court reporter shall be allowed to attend any portion of a deposition in which protected information is used or elicited from the

deponent. In-house technical advisors according to paragraph 4(f) may not attend any portion of a deposition in which highly confidential information is used or elicited from the deponent.

21. If a party designates information as protected information on the record at a deposition, the court reporter, to the extent possible, shall segregate into separate transcripts information designated as protected information from information not so designated. The page numbers of the separate transcripts shall be consecutive so as to permit the pages to be merged into a complete transcript at the time of trial or as the Court may direct.

Inadvertent Failure to Designate

22. The inadvertent failure by a producing party to designate specific documents or materials as containing protected information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. Upon notice to the receiving party of such failure to designate, the receiving party shall cooperate to restore the confidentiality of the inadvertently undesignated information.

Inadvertent Production of Protected Documents

23. The inadvertent production of documents or materials subject to the attorney-client privilege or work-product

immunity shall not constitute a waiver of privilege or immunity. After receiving notice from the producing party that documents or materials subject to the attorney-client privilege or work-product immunity have been inadvertently produced, the receiving party shall not review, copy, or otherwise disseminate the documents or materials, nor shall it disclose their substance. In addition, the receiving party shall return the documents or materials and all copies within five (5) business days from receiving notice. These provisions shall not apply, however, unless the producing party notifies the receiving party of the inadvertent production before the document is used at a deposition or attached to a court submission.

Challenges to Protected Information Designation

24. A party shall not be obligated to challenge the propriety of a protected-information designation at the time made, and a failure to do so shall not preclude a subsequent challenge thereto. In the event that a party disagrees at any time with a protected-information designation made by another party, the parties shall make a good faith attempt to resolve the dispute on an informal basis. If the parties cannot resolve the dispute, the objecting party may seek appropriate relief from the Court, and the designating party shall have the burden

of proving that its protected-information designation is proper.

Filing of Protected Information

25. The clerk of the Court is directed to file and maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, as containing or revealing protected information if the filing includes the information required in paragraph twenty-six.

26. In the event that a party wishes to use any protected information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court, such paper shall be enclosed in a sealed envelope or other appropriate container. The sealed envelope or other appropriate container shall:

- (a) show the caption of this action;
- (b) identify its contents; and
- (c) include the following legend:

PROTECTED INFORMATION SUBJECT TO PROTECTIVE ORDER

This envelope [on container] is sealed pursuant to court order and contains confidential and proprietary information. This envelope [or container] was filed by [name of party] and may not be opened, nor

may its contents be displayed or revealed, except by court order or by written stipulation of the parties.

Advice to Clients

27. Nothing in this protective order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to this action and, in the course thereof, referring to or relying upon his or her examination of protected information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any protected information if such disclosure would be contrary to the provisions of this protective order.

Miscellaneous

28. No party shall be responsible to another party for any use made of information that was produced and not designated as protected information.

29. Nothing in this protective order shall prejudice the right of any party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

30. Nothing in this protective order shall prejudice the right of any party to seek at any time a further order modifying this protective order.

31. Nothing in this protective order shall prejudice the right of any party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any protected information.

32. In the event that a new party is added, substituted, or brought in, this protective order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this protective order.

33. Nonparties who produce information in this action may avail themselves of the provisions of this protective order.

34. Within ninety (90) days after the termination of this action (including any appeals), each document and each other tangible thing that contains or reveals protected information and any copies, abstracts, summaries, notes, or other records regarding the contents of any protected information shall be either (a) returned to the attorney of record for the producing party or (b) destroyed with a representation of such destruction being made to the attorney of record for the producing party. Notwithstanding the foregoing, outside counsel for a receiving party may retain protected information to the extent such protected information is contained in counsel's work product, in

correspondence between outside counsel, or in copies of pleadings and materials filed with the Court.

35. Sixty (60) days after the termination of this action (including any appeals), any protected information that was filed under seal with the clerk of the Court will be returned to the attorney of record for the filing party. See N.D. TEX. LOC. CIV. R. 79.4.

36. The provisions of this protective order shall survive and remain in full force and effect after the termination of this action (including any appeals).

37. This protective order may be amended as need may arise by written agreement of the parties without prior leave of the Court.

Unless this order includes a clause that explicitly states that a particular local civil rule is modified as applied to this case, nothing in this order shall be construed to modify the provisions, operation, or effect of any local civil rule of this Court.

SIGNED November 18, 2008.


TERRY R. MEANS
UNITED STATES DISTRICT JUDGE

The foregoing protective order is agreed to and accepted as

to both form and substance.

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

GALDERMA LABORATORIES, L.P. §
and GALDERMA S.A., §
v. § ACTION NO. 4:08-CV-115-Y
ACTAVIS MID-ATLANTIC, L.L.C., §

DECLARATION AND AGREEMENT TO BE BOUND

I, _____, declare and state under penalty of perjury that:

1. My address is _____.
2. My present employer is _____
and the address of my present employer is _____.
3. My present occupation or job description is _____.
4. I have received a copy of the Stipulated Protective Order in this action, which order was entered on _____.
5. I have carefully read and understand all of the provisions of the Stipulated Protective Order.
6. I will comply with all of the provisions of the

Stipulated Protective Order.

7. I will hold in confidence, will not disclose to anyone not qualified under the Stipulated Protective Order, and will use only for purposes of this action, any Protected Information that is supplied to me.

8. Upon completion of this action (including appeals), I will return each document and each other tangible thing that discloses or reveals any Protected Information to the attorney who provided such document or other tangible thing to me. Moreover, upon completion of this action (including appeals), I will deliver any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information to the attorney who provided such Protected Information to me.

9. I understand that if I violate the provisions of the Stipulated Protective Order, I will be in violation of a Court order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages.

10. I hereby submit to the jurisdiction of the United States District Court for the Northern District of Texas for the purpose of enforcement of the Stipulated Protective Order.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Date: _____
